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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Vaccines and Related Biological Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 11, 2000, 8 a.m. to 5:30 p.m. and on May 12, 2000, 8 a.m. to 3 p.m.

Location: Holiday Inn, Kennedy Grand Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Contact Person: Nancy T. Cherry or Denise H. Royster, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12391. Please call the Information Line for up-to-date information on this meeting.

Agenda: On May 11, 2000, the committee will hear updates on activities in the Office of Vaccines Research and Review. The committee will also be informed of issues pertaining to the status of vaccines for the prevention of rotavirus disease. On May 12, 2000, the committee will review issues relating to the development of policy regarding the use of various types of neoplastic cells as substrates for vaccine manufacture.

Procedure: On May 11, 2000, from 9:15 a.m. to 1:45 p.m., and on May 12, 2000, from 9:15 a.m. to 3 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by May 4, 2000. Oral presentations from the public will be scheduled between approximately 12:20 p.m. to 12:50 p.m. on May 11, 2000, and between approximately 10:35 a.m. to 10:50 a.m. and between approximately 1:30 p.m. to 1:45 p.m. on May 12, 2000. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 4, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

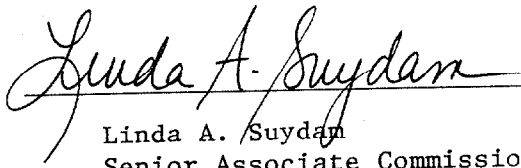
Closed Committee Deliberations: On May 11, 2000, from 8 a.m. to 9 a.m., and from approximately 1:45 p.m. to 5:30 p.m., and on May 12, 2000, from 8 a.m. to 9 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information. (5 U.S.C. 552b(c)(4)). These portions will be closed to permit discussion of pending investigational new drug applications or pending product licensing applications.

FDA regrets that it was unable to publish this notice 15 days prior to the May 11 and 12, 2000, Vaccines and Related Biological Products Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Vaccines and Related Biological Products Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

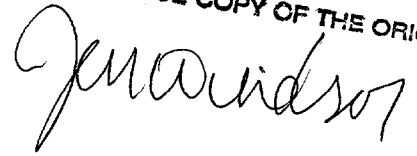
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Dated: April 21, 2000



Linda A. Suydam
Senior Associate Commissioner

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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